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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,216	06/20/2003	Timothy A. Ringeisen	KN P 0119	7299

7590 07/28/2004

Jeffrey C. Kelly, Esq.
Kensey Nash Corporation
55 East Uwchlan Avenue
Exton, PA 19341

EXAMINER

ZEMEL, IRINA SOPHIA

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

cf

Office Action Summary	Application No.	Applicant(s)	
	10/601,216	RINGEISEN ET AL.	
	Examiner	Art Unit	
	Irina S. Zemel	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10-8-2003</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-8, 12, and 16-28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 6,179,872 to Bell et al., (hereinafter "Bell")

Bell discloses centrifuged biocompatible compositions and a method for producing biocompatible polymer material by providing a slurry of polymer fibers, centrifuging the suspension liquid and removing product thus obtained from the centrifuge, as per claims 1, 22 and 24. See Column 9, lines 17 to 67. The reference further discloses various biocompatible materials suitable for implantations and containing polymer fibers, as per claim 16. See ENTIRE disclosure, for example, claim 1. The polymeric materials suitable for the invention disclosed in Bell include various biopolymers such as collagens, thus

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meeting limitations of claims 4, 17, and 25. See column 4, line 47 to column 5, line 35. The concentration of collagen in slurries disclosed by the reference is under 10 % as per claim 2. In column 9, lines 64-67, the reference specifically discloses that the slurry containing collagen fibers can be applied by centrifugal force or rotating motion to dishes and tubes. As a result of this procedure, mats in the form of the dishes or tubes are created, thus satisfying the limitation of claim 12. The reference further explicitly teaches addition biologically active agents to the slurries, as per claims 5, 18, and 26, see column 6, line 13 to column 7, line 25 and also addition of biocompatible particulate material such as calcium phosphates, meeting limitations of claims 6-7, 19-20, and 27-28. See column 10, lines 24-39. The reference further discloses that the mats can be reinforced with reinforcing materials, such as fibers of woven fabrics (mesh) as per claim 21. See column 11, line 27 to column 12 line 33. The reference further states that the mats according to the invention can be used for replacement or repairing various tissues, including bone tissue as per claim 23. See column 1, lines 51-52.

Applicants should note that claim 28 does not clearly recite any necessary limitation. The language "may be injected", does not necessarily mean that the composition is, in fact, injectable. It is suggested that the claim is rewritten to more specifically claim the property of the composition.

The reference does not explicitly teach whether the polymer fibers are interlaced or interlocked as per claims 1, 8 and 22; whether the fibers in the biocompatible compositions are of sufficient quantity and processed sufficiently

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to retard dislocation of individual polymer fibers upon implantations as per claim 16; and whether the disclosed mats are viscous and self-supporting an per claim 24 . However, from the disclosed applications of the mats and their physical tear properties disclosed in illustrative examples and throughout the specification, it is reasonable believed that the fibers of the mats are inherently, at least partially, interlocked and, thus, sufficiently processed to retard individual fiber dislocation, and the compositions are, inherently, self-supporting compositions. The burden is shifted to the applicants to provide factual evidence to the contrary.

Claims 1, 2, 4, 16, 17, 22, 24-25 and 28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent 3,742,955 to Battista et al., (hereinafter "Battista").

Battista discloses a method of preparing biocompatible materials by centrifuging a slurry containing about 9.7 weight percent of fibrous collagen. Dried products are removed from the centrifuge and further processed. See examples 1—V, and X.

The reference does not explicitly teach whether the polymer fibers are interlaced or interlocked as per claims 1, 8 and 22; whether the fibers in the biocompatible compositions are of sufficient quantity and processed sufficiently to retard dislocation of individual polymer fibers upon implantations as per claim 16; and whether the disclosed mats are viscous and self-supporting an per claim 24 . However, from the disclosed examples that include mixing of the slurries from prolonged time prior to application of centrifuge force, it is reasonable

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believed that the fibers of the mats are inherently, at least partially, interlocked and, thus, sufficiently processed to retard individual fiber dislocation. It also reasonable believed that the intermediate products containing 30-40 % by weight of collagen are self-supporting viscous products. The burden is shifted to the applicants to provide factual evidence to the contrary.

Claim Rejections - 35 USC § 103

Claims 3, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell.

The disclosure if the Bell reference is discussed above. The reference does not address the concentration of the slurries prior to application of the centrifugal force to form to slurries to form the final product. Thus, the reference implies that any diluted concentrations of slurries are suitable for the invention with reasonable expectation of adequate results. Furthermore, variations in slurry concentrations is considered to be an obvious modification of the process to facilitate the dispersion and/or drying of the resulting product.

The reference also does not explicitly disclose that the centrifuge contains a reinforcing material. However, as discussed above, the reference explicitly teaches the biopolymer matts may be reinforced with various reinforcing materials such as treats and fabrics. Placing such materials in the centrifuge along with the slurry would have been an obvious, if not necessary, step for introducing such reinforcing materials to the resulting fibrous matts. The

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invention as claimed, thus, would have been obvious from the disclosure of the Bell reference.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell in combination with US Patent 4,066,083 to Ries.

The disclosure of the Bell reference is discussed above. The reference is silent as to the steps of packaging, sterilizing and rehydrating the resulting biocompatible polymer materials. However, the examiner takes a note that it is well known in the art that any material (including those based on collagen polymers) that is used for treatment, replacement or repairing of living tissue is usually packaged, sterilized and kept under sterile conditions after producing such material and prior to using it. See, for example, Ries, column 4, lines 46-59.

Claims 5—8, 18-20 and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Battista in combination with Bell.

The disclosure of the Battista reference is discussed above. The reference does not disclose addition of biologically active agent or biologically active particulate. However, addition of those components to the collagen products disclosed by Battista would have been obvious as per teachings of Bell, who discloses that addition of biologically active agent or biologically active particulate improves physical properties of the fibrous collagen products and imparts various biologically active properties to the final products.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irina S. Zemel whose telephone number is (571)272-0577. The examiner can normally be reached on Monday-Friday 9-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571)272-1078. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ISZ



James J. Seidleck
Supervisory Patent Examiner
Technology Center 1700